

Alessandro Ferroni

RESULTS & PEOPLE DRIVEN ENGINEERING LEADER

2021 2023 – Site Engineering Director, in GSK Vaccines Rosia (SI) Italy (Vaccines industrial site + R&D site). Capital Plan (30m/y CAPEX), site Utilities & Facilities (including Carbon Footprint program), Validation, Reliability and Automation. Leading a team of 140 Engineers and Technicians with 10 direct reports. 22m/y OPEX budget (including 10m/y Utilities costs). Leading successful Reliability improvement projects (flywheel UPS for Aseptic Facility power protection, major Chillers replacement to ensure continuity & emissions optimization,...) and significant cost savings for the site (4m in 2022).

2019 2020 – Director of Engineering, Maintenance and Utilities (EMU) at Pfizer (Wyeth) Catania Site, Italy. Plant Maintenance, Facilities, Utilities, and Capital Projects. Leading a team of 120 Engineers and Technicians with 8 direct reports in a Aseptic Lyo and Liquid Formulation and Filling site for Penicillin and Non Penicillin based antibiotic DP production.

2016 – 2018 Engineering Director, Dompé farmaceutici SpA, L'Aquila, Italy. Plant Maintenance and Engineering operations. Leading the company effort of a over 30M€ Site and Production Capacity expansion project. Leading Engineering efforts for successful first FDA Site approval and Drug Product approval at Dompé.

2011 – 2015 Engineering Sr.Manager, Dompé farmaceutici SpA, L'Aquila, Italy. Utilities, Plant Maintenance and Engineering operations. Leading the company effort of large capex investments in Coated Granulated Solids new product industrialization (Okitask) and to bring the first own Biotech API to the market. Process scale-up, Industrialization and validation in aggressive time to market using Quality Risk Management approach.

• Successfully Built new 10M€ biotech plant with a record aggressive construction timeline of 12 months from green-field to inspection (Upstream, Downstream, Cell Banking & Utilities).

• Engineering and Maintenance of the Pharmaceutical Industrial site (liquid and solid oral products) including tens of investment projects in new process and packaging lines and efficiency improvements. Key results: increased the overall Production Equipment OEE by 10% in 3 years.

• Managing Engineering annual budget (7M€ expenses and 15M€ capital) including Central Utilities and Facilities development.

2011. Head of Engineering at Intendis Manufacturing (Bayer Healthcare), Segrate (MI) Italy. Leading a team of 36 Engineers and Technicians in a large Semisolids GMP Plant (85M piece/year).

- •Capital investments about 3M€/year.
- •Leading Maintenance of Production Plant Process, Packaging and Utilities teams.

2006 – 2010. Site PCS & Electrical Manager at Bayer Healthcare Biolgical Products Div, Berkeley-CA (USA). Leading a multinational team of 15 Engineers and Project Managers and about 30 professional contractors.

• Responsible of multiple Process Control and Utilities Projects (ranging from 0.5 up to > 10 Mio \$)

• Provided Plant PCS & Electrical support to a 1600 people complex Biotech industrial site for production of one of the largest industrially produced recombinant proteins (injectable R-FVIII).

• Implemented new plant support responsibilities, focusing the team on internal customers needs trough teambuilding and people development, successful implementation of multiple capital projects, development and implementation of a new Plant Automation Strategy including MES-DCS integration for paperless Electronic Batch Record, implementation of new products processes, new packaging lines, upgrade of the huge (> 100 servers) DCS control system of the entire production process,

- Negotiation of key strategic engineering and support contracts (up to 4 Mio \$ /year).
- Other West Coast Bayer site projects (Emeryville-CA, Sunnyvale-CA, Seattle-WA)

2005 - 2006. Head of Information Systems and Process Control Systems at Bayer Biologicals S.r.I, (Italy). Added accountability of the Company Information Systems (Network and Infrastructure, Laboratory Information Management System, etc.), following the successful partnership project to implement the MES System for the Materials Management of the site and to prepare implementation of Electronic Batch Record System.

2001 – 2005. Site PCS Engineering Manager at BAYER Biologicals S.r.I. Leading a team of technicians and multiple contractors teams, with responsibilities including:

- Electrical Power distribution, PCS Maintenance, Calibrations, specification, selection, implementation and validation of Industrial automation systems.
- Project manager for new Packaging Lines including new Medical Devices and multiple Automation projects including Validation, Equipment Qualification of existing and new equipment in Utilities, Packaging and QC.

• Vendors GMP audits. Computer System Validation. Development and rollout of validation procedures including Electronic Signatures and Electronic Records compliance.

2001 in Bayer Corp. Clayton, North Carolina (USA) PCS Engineer in the project Team for commissioning and qualification activities of Immunoglobulin production plant.

2000 – 2001. In BAYER Biologicals S.r.I, Italy as site PCS Engineer in the IGIV-C Project Team developing a greenfield site project in the Foster Wheeler Engineering team.

1998 - 2000 BARILLA Alimentare S.p.A, (www.barilla.it) Project Manager for new production plants in Central Engineering Direction, Industrial Automation Unit.

• From design to project engineering and coordination of the team of professionals for the prototyping and construction of internally developed 'High Speed Flexible Packaging Islands', including deploy, commissioning and startup in various production sites of the Company.

• Technical and economical Responsible for the electrical and automation (supervision and process control systems) of large scale new production plants, including fully automated Warehouse, Automatic Guidance Vehicles, etc.. from technical requirements, design specifications, timing, costing, coordination of multiple international vendors in the construction site till commissioning and validation in different production sites of the company.

• Successful projects including: New Panbauletto Line in Melfi (PZ), New High Speed Packaging lines in Cremona, Novara, Mantova sites.

• Automation Strategies: understanding the process, evaluating the technology options, facilitating and prioritising improvement ideas, assessing the impact on the production processes of the strategy and developing the strategy.

1996 – 1998 Technical Office COLUSSI S.r.I. (a 500 employees Food Company www.colussigroup.it).

• Production plants improving projects, design optimization, increase of flexibility of production and packaging lines, in a 15 lines fully automated industrial plant. Support to Marketing and R&D for industrialization of new products and packaging solutions.

• Responsible of the implementation of ISO9000 and HACCP (Hazardous Analysis and Critical Control Points) for company's Technical Area.

• Project manager of a new 3000 m2 Production facility, from building construction to implementation of the new process and packaging equipment and fully automated Warehouse, technical specifications, vendors coordination, installations and commissioning.

• Project manager for new Technical Utilities Plants such as Electrical MT-BT transforming stations, Industrial Gas decompression stations and distribution, Compressed Air generation Stations and distribution, etc. Project manager for implementation, in a SCADA-MMI structure, of the control system developed during the Research Project with the University.

- **1996 1997, Research Projects with various University Schools** (Chemistry, Pharmacy, Medicine) on applications of Artificial Intelligence (Neural Networks) for modeling, identification and simulation in different fields (pharmacological studies, image processing and pattern recognition for medical diagnostic instruments, automatic fault detection).
- **1995-1996 University of Perugia, Research Project with Artificial Intelligence tools (**Neural Networks, Fuzzy and Neural-Fuzzy, Adaptive Systems, Expert System and Genetic Algorithms) to develop an automated process optimization and control system of and Industrial Production Plant, aimed at reducing production rejects and the improvement of product quality. Hired as consultant of the University for development of A.I. based SCADA systems for on-line computer supervision and control of industrial processes.

Scientific Papers & Patents

- Italian Patent MI2014A000732 "Setto per Camere bianche, camera bianca e procedimento per la predisposizione della stessa"
- "From Lab to Industrial Plant: Fast Track and flexible approach", presented at the CHEM-MED The Mediterranean Chemical event, Milan Fair Center 24-26 Sept 2013
- "Distributed control systems and process monitoring", at the Omeostasys, technology for process control, Unione Industriali, Fermo Italy, May 6, 1998.
- "Modeling of the Proofing Process in a Continuous Bread-making Industrial Plant using Neural Networks." ICNN - IEEE International Conference on Neural Networks, Houston Texas, USA, Jun9-12 '97
- *"Heart rate variability assessed by Neural Networks as PP variability"*, at the 4th European Conference on Engineering and Medicine, Warsaw, Poland, May 25-28, 1997.
- "Modeling, Identification and Control of the Proofing Process in a Bread-Making Industrial Plant: A Soft Computing Approach", presented at the IASTED International Conference on Modeling, Identification and Control, at the Innsbruck Kongresshaus, Innsbruck, Austria, Feb17-19, 1997.
- "Modeling of the Proofing Process in a Continuous Bread-Making Industrial Plant using Neural Networks", presented at the MIM (Manufacturing Industrial Modeling) Conference, Vienna, Austria, Feb. 3rd 1997.

Education

Laurea University degree (MS) in Electronic Engineering - Applied Electronics and Industrial Automation, 104/110, University of Perugia, Italy. Thesis on "Advanced Algorithms for the Modelling and Optimal Control of a Continuous Industrial Production Line". Licensed as Doctor Engineer in Italy.

Memberships

ISPE (20+ years member),

SPS - Italy (Messe Frankfurt) Member of the Scientific Committee 2015-2019.

Individual Courses

- 1996 "Optimization Algorithms and Models" (IBM, Italian Operative Research Organization).
- 1997 "Technical Service Coordinator", by Galgano Group, Milan
- 1997 "Statistical Process Control", local Association of Industrialists.
- 1998 "Adept multitasking real time software systems for Robotics applications"
- 1998 "GMP Good Manufacturing Practice" Company Course (Cisita-Barilla)
- 1998 "EU legislation on health and safety practices in Construction Sites (Codes of Practice, Italian laws 626/94 and 494/96)" Company Course (Cisita-Barilla)
- 1999 Siemens, Industrial Automation School, course in PLC Systems projects
- 2001 Company Courses on GMP and Industrial Safety c/o Bayer Corp. USA, Pharmaceutical Division, Biological Department, Clayton, NC (USA)
- 2001 'Computer System Validation and GAMP' by ISPE, Newark, NJ (USA)
- 2001 'CFR21 part11 Electronic Records, Electronic Signatures' by ISPE, Newark, NJ (USA)
- 2003 "Italian Pharmaceutical companies and CFR 21 Part 11" by ISPE and PDA, Milan (Italy)
- 2004 "RSPP" (Company Resp. for Work Safety by italian law 195/2003) by Confindustria Siena
- 2004 "Communication and Problem Solving" by Confindustria Siena

2006–2010 Multiple Courses in US: People Leadership, Managerial Coaching, Project Management, KPI and Business Objectives, Plant Safety, Finance for Non-financial Mangers, Oxley Sarbanes Act, etc.

Languages

Italian mother language. English fluent. Fair knowledge of German and Croatian.

Personal

Married. Two US-born daughters.

1990-1993 President of Youth branch of Lions Club in Perugia, active in Charity and Humanitarian events. Volunteer freelance journalist and reporter from Croatia during 1990-1995 war, for local newspapers and televisions. Licensed Ham-Radio (hobby construction of radio antennas). Practiced Sports: Ski, scuba diving (license), parachuting (license).

Privacy consent: Autorizzo il trattamento dei miei dati personali ai sensi dell'art. 13 Dlgs 196 del 30 giugno 2003 e dell'art. 13 GDPR (Regolamento UE 2016/679) ai fini della ricerca e selezione del personale.